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EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,900	BUCHACHER ET AL.	
	Examiner	Art Unit	
	David A. Saunders	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-28* is/are pending in the application.

4a) Of the above claim(s) *23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-22 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/20/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1 and 3-28 are pending.

RESPONSE TO ELECTION/RESTRICTION

Applicant's election without traverse of Group I (claims 1, 3-22 and 24-28) in the reply filed on 5/9/08 is acknowledged. Claims 1, 3-22 and 24-28 are under examination.

REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH

Claims 1, 3-22 and 24-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, step c), line 1 thereof, "the supernatant solution" lacks antecedent basis, since step b) has recited no "supernatant solution".

In claim 1, step c), lines 1-2 thereof, "under conditions..." is unclear because there is no statement of what the "conditions" are intended to achieve.

In claim 8, line 2, "the second anion-exchange chromatography" lacks antecedent basis. Base claim 6 has referred to "two different anion exchange resins" but has not specifically stated whether these are packed together in one chromatography column, or whether these are packed separately in two chromatography columns. Thus recitation of "the second..." is unclear. Also, neither base claim 1 nor 6 have recited anything about "chromatography".

In claim 9, line 2, "the anion-exchange chromatography flow-through" lacks antecedent basis. Base claim 1 has not recited anything about "chromatography" or about a "flow-through".

In claim 10, line 2, "the flow-through" lacks antecedent basis. Base claim 1 has not recited anything about a "flow-through".

In claim 10, line 2, "the first anion-exchange chromatography" lacks antecedent basis. Base claim 1 has referred to "at least one anion exchange resin" but has not specifically stated, for the case in which there is more than one resin, whether these are packed together in one chromatography column, or whether these are packed separately in two chromatography columns. Thus recitation of "the first..." is unclear. Also, base claim 1 has not recited anything about "chromatography".

In claim 12, line 2, "the caprylate treatment" lacks antecedent basis. Base claim 1 has not recited anything about a "treatment".

In claim 14, line 2, "the second anion-exchange chromatography" lacks antecedent basis. Base claim 1 has referred to "at least one anion exchange resin" but has not specifically stated, for the case in which there is more than one resin, whether these are packed together in one chromatography column, or whether these are packed separately in two chromatography columns. Thus recitation of "the second..." is unclear. Also, base claim 1 has not recited anything about "chromatography".

In claim 15, line 2, "the flow-through" lacks antecedent basis. Base claim 1 has not recited anything about a "flow-through". Further, one does not know if the claim is referring to "the flow-through" of the first or the second anion-exchange step.

In claim 21, "adjusting the pH of the IgG solution to about 3.5 to about 6.0" is unclear. There have been some many steps recited in the chain of dependencies leading to claim 21, that one cannot determine at which of the steps there is to be an "adjusting" of the pH. Furthermore, if an "adjusting" of the pH is to occur as a final step, then the claim must recite --adjusting the pH of the concentrate--, rather than "adjusting the pH of the IgG solution".

In claim 22, if "sterile filtering and filling the IgG solution" is to occur as a final step, then the claim must recite --sterile filtering and filling the concentrate--, rather than "sterile filtering and filling the IgG solution".

In claim 27, "wherein the pH is about 4.0" is unclear. There have been some many steps recited in the chain of dependencies leading to claim 27, that one cannot determine at which of the steps "the pH is about 4.0".

REJECTION(S) UNDER 35 USC 112, FIRST PARAGRAPH

Claims 3, 8-11, 13-22 and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Each of Claims 3, 8-10, 13-15, 19-21 and 27-28 contain new matter. All claims depending therefrom are rejected.

Claim 3 contains new matter by reciting "about 6.7 to about 6.9." There is no support for "about" in para. [0023] or [0038] of US 2007/0173638, which is the publication of applicant's disclosure.

Claim 8 contains new matter by reciting "about pH 6.8." There is no support for "about" in para. [0027] of US 2007/0173638. While para. [0038] does recite "6.8 +/- 0.1" this recitation does not support "about 6.8", since the latter can be broader than the former.

Claim 9 contains new matter by reciting "about 60 to about 90". There is no support for "about" in para. [0027] of US 2007/0173638.

Claim 10 contains new matter by reciting "about 4.5 to about 8 hours". There is no support for "about" in para. [0027] of US 2007/0173638.

Claim 13 contains new matter by reciting "about 6.7 to about 6.9". There is no support for "about" in para. [0023] or [0038] of US 2007/0173638.

Claim 15 contains new matter by reciting "about 3.5 to about 4.5". There is no support for "about" in para. [0028] of US 2007/0173638.

Claim 19 contains new matter by reciting "to about 5 or about 10 % (w/v)". There is no support for "about" in para. [0030] or [0038] of US 2007/0173638.

Claim 20 contains new matter by reciting "about 200 to about mOsmol/kg." There is no support for "about" in para. [0030] of US 2007/0173638.

Claim 21 contains new matter by reciting "about 3.5 to about 6.0." There is no support for "about" in para. [0030] of US 2007/0173638.

Claim 27 contains new matter by reciting "about 4.0." There is no support for "about" in para. [0028] of US 2007/0173638.

Claim 28 contains new matter by reciting "about 37 degrees C." There is no support for "about" in para. [0029] of US 2007/0173638. While para. [0029] does recite "37 degrees C +/- 1", this recitation does not support "about 37", since the latter can be broader than the former.

REJECTION(S) UNDER 35 USC 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-7 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lebing et al (EP 0,893,450).

Lebing et al show all steps of instant claim 1 at pages 3-4. Step 2) of their process reads as:

> 2) Dissolving immunoglobulins into solution by lowering the mixture to pH 3.8 to 4.5, preferably 4.2, by the addition of acid, preferably acetic acid, with further vigorous mixing.

Lebing et al thereby disclose that the pH at this step can be as high as 4.5, which is considered to be encompassed by recitation of "about 4.6" in step a) of instant claim 1 (Note, also that claims 2-3 of Lebing et al teach that the upper end of this pH range can be as high as 4.6). A pH of "about 4.6", as recited in instant claim 1, is thus anticipated by Lebing et al, if one considers that their teaching of pH 4.5 is within the four corners of the reference. Alternatively, this aspect of instant claim 1 would have been obvious over Lebing et al, if one considers that their teachings of pH 4.5/4.6 would have been one pH selected from a range of pH values taught.

Step 3) of the process of Lebing et al reads as:

> 3) Adding a source of caprylate ions (e.g., 40% w/v sodium caprylate in water) to a final concentration of 15 mM to 25 mM, preferably 20 mM, and adjusting the pH up to 5.0 to 5.2, preferably 5. 1, with a base (such as 1 M NaOH).

Lebing et al thereby disclose that the pH at this step can be as low as 5.0 which is considered to be encompassed by recitation of "about 4.95" in step b) of instant claim 1. This aspect of instant claim 1 is thus anticipated by Lebing et al, if one considers that their teaching of pH 5.0 is within the four corners of the reference. Alternatively, this aspect of instant claim 1 would have been obvious over Lebing et al, if one considers that their teaching of pH 5.0 would have been one pH selected from a range of pH values taught. Step 4) of the process of Lebing et al shows the formation of a precipitate, as required by the concluding phrase of step b) of instant claim 1.

While applicant's disclosure appears to contemplate that the instant invention does not involve a "pH shift" or "pH swing" from step a) to b), like the method of Lebing et al, the Office finds that the claim language, in fact permits such a "pH shift" or "pH swing" from step a) to b). This is because the "intermediate solution" of step b) has a

narrower recited pH range than the recited pH range of the "starting solution" of step a) --i.e. the narrower recited pH range of step b) encompasses only the upper portion of than the recited pH range of step a). Thus there are, necessarily, embodiments in which the pH would be adjusted upward in going from step a) to step b) of instant claim 1. The leeway for such a "pH shift" is further expanded by virtue of the fact that applicant has amended claim 1 to recite "about" before each recited pH value; thus in step a) the pH can be lower than 4.6, and in step b) the pH can be higher than 4.95.

Step 4) of the process of Lebing et al correspond to step c) of instant claim 1.

Step 9) of the process of Lebing et al corresponds to step d) of instant claim 1; note, also, the pH value of 5.1 as being the pH at which one applies the solution to a "first anion exchanger" (page 4, lines 32-33).

Claim 1 is thus anticipated by or obvious over Lebing et al.

Regarding claim 4, note Lebing et al at page 4, wherein steps 5)-6) correspond to repeating instant steps b) and c) at leas tone time.

Regarding claim 5, note Lebing et al at page 5, lines 1-20 teach preparation of the instant "starting solution" form a Cohn fraction II+III paste, which is art recognized as being derived from plasma.

Regarding claim 6, note Lebing et al at page 4, lines 21-23, which teach that the IgG fraction(containing antibodies) is in the "flow through and wash fractions" 9 -- i.e. is not bound to the anion exchange columns). Note also page 5, teaches that the two anion exchange columns are "strong" and "weak anion exchange" columns, And thus must inherently have "different anion exchange resins".

Regarding claim 7, Lebing et al teach purification of IgG throughout.

Regarding claim 12, Lebing et al teach that "non-enveloped viruses are capture on the filter pad" (page 4, line 17).

PRIOR ART OF INTEREST

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Parkkinen (WO 2005/073252) teaches a method in which Fraction II + III paste is dissolved and brought to a pH of 4.8. See Example 1 at page 14. Parkkinen thus shows the "intermediate solution" of instant claim 1, step a). However, Parkkinen does not show step b) of instant claim 1. More particularly, Parkkinen teaches that caprylic acid, rather than a caprylate salt, is to be added to the solution containing the dissolved paste. See page 10, line 25-page 11, line 3. Instant claim 1, step b) requires the addition of "caprylate" rather than caprylic acid. Thus Parkkinen is not cited against the instant claims.

It is further noted that Parkkinen does teach that one may use a caprylate salt, rather than caprylic acid. See page 11, lines 1-2. However, Parkkinen therein refers to certain US Patents which teach addition of a caprylate salt. One such referenced patent is US 6,307,028, which is of the same patent family as that of EP 0,893,450, cited supra. Since one would need to modify the teachings of Parkkinen by referring to US 6,307,028 or EP 0,893,450, the combination Parkkinen with one of these references is not cited against the instant claims. EP 0,893,450 has been cited supra, and by itself it is sufficient.

Lebing et al (US 6,307,028, cited on PTO-892) has been noted supra as being of the same patent family as that of EP 0,893,450.

Parkkinen (US 2007/0244305, cited on PTO-892) has the same disclosure as WO 2005/0732252, noted supra.

Other references cited on PTO-892 have been cited in lieu of references lined out on PTO-1449, which references were not in the imaged file record.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eilleen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 7/5/08 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644